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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,514	09/28/2001	Reid Warren von Borstel	1331-353	2510

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NIXON & VANDERHYE P.C.
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER	
OWENS JR, HOWARD V	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,514	BORSTEL ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *1-9,30-33 and 35-39* is/are allowed.

6)☐ Claim(s) *10-19 and 21-29* is/are rejected.

7)☒ Claim(s) *9,20 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-15-2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim 20 is objected to as it depends from itself.

Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 depends from both claim 16 and claim 18; however, it fails to further limit the subject matter of these claims and actually sets forth a broader composition than the parent claim(s).

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-15 and 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 25, 30, 50 and 55 of U.S. Patent No. 5,470,838 ('838); claims 1-4 and 12-15 of U.S. 6,274,563 ('563); claims 1-8 of US 5,583,117('117); claims 1-9, 13,18-23 and 27 of US 6,316,426 ('426). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11-15 and 21-29 are generic or synonymous to all that is recited in claims 1-15, 25, 30, 50 and 55. That is claims 1-15, 25, 30, 50 and 55 of U.S. Patent No. 5,470,838 ('838); claims 1-4 and 12-15 of U.S. 6,274,563 ('563); claims 1-8 of US 5,583,117('117); and claims 1-9, 13,18-23 and 27 of US 6,316,426 ('426) fall entirely within the scope of claims 11-15 and 21-29.

Claims 10-15 and 21-29 are drawn to a method of delivering exogenous uridine or cytidine to the tissue of an animal, treating cardiac insufficiency, myocardial infarction, hepatopathy, Parkinson's disease, cerebrovascular disorders, comprising administering acylated uridine or cytidine.

Claims 1-15, 25, 30, 50 and 55 of '838 and claims 1-8 of '117 are drawn to methods of delivering exogenous uridine or cytidine to the tissue of an animal, treating cardiac insufficiency, myocardial infarction and cirrhosis of the liver via administration of acylated uridine or cytidine. Cirrhosis of the liver is encompassed by the language of instant claims 21 and 22 wherein hepatopathy is claimed.

Claims 21-29 are drawn to the treatment of diabetes with an acylated cytidine or uridine. Claims 1-4 and 12-15 of '563 encompass the diabetes species set forth in instant claims 21-29 as they are drawn to a method of treating diabetes using acylated uridine or cytidine analogs. The Parkinson's disease and cerebrovascular disorder species set forth in claims 21-29 is anticipated by 1-9, 13,18-23 and 27 of '426.

Claim Rejections – 35 U.S.C. 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cardiac insufficiency, myocardial infarction, hepatopathy, Parkinson's disease, cerebrovascular disorders, does not reasonably provide enablement for the treatment of any pathological and physiological condition affecting tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breath of the claims and the
8) level of skill in the art.

An Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements, while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

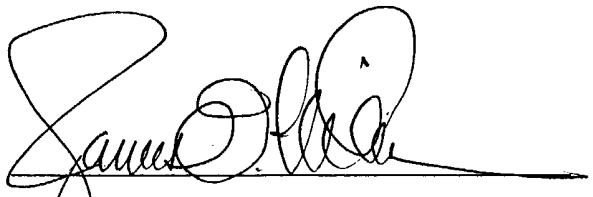
The instant claims are drawn to the treatment of unspecified physiological and pathological conditions of tissue wherein the breadth of the claims requires guidance and support for a multitude of conditions that affect tissue. The claim amounts to a panacea for any physiological or pathological condition affecting tissue, wherein the term tissue can be broadly construed to be skin, organs, muscle etc. The support in the specification is limited to the prior art's recognition that the presence of certain nucleotide levels can have an affect on conditions such as diabetes, cirrhosis, myocardial infarction and certain cerebrovascular disorders. The data in the specification supports the delivery of acylated cytidine and uridine analogs; however, there is no suggestion that the delivery of these agents will treat any physiological or

pathological condition that affects tissue. The acylation of the nucleotides improves the bioavailability, but there is no support that the increase in bioavailability reasonably extrapolates to the treatment of any pathological or physiological condition affecting tissue. The prior art used to support the biological affects of uridine and cytidine is limited to specific *in vitro* and *in vivo* affects related to specific conditions and there is no suggestion in the prior art that the administration of these nucleotides treats every conceivable pathological or physiological condition of tissue. Thus any claims to the broad efficacy of the claimed acylated nucleosides should be properly supported by the instant specification. The specification addresses the use of the acylated compounds to treat cardiac insufficiency, liver damage and myocardial infarction; however, these limited examples do not support the treatment of any pathological or physiological condition of the tissue. Without proper guidance and adequate support in the specification, one of skill in the art would be subject to undue experimentation in the practice of the invention as claimed.

Allowable Subject Matter

The acylation of the 2', 3', 4' and 5' analogs of uridine and cytidine presented in claims 1-8, 30-33 and 35-39 appear to be an unobvious improvement over the prior art of record.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.